

With respect to claim 26, it is respectfully submitted that this claim should be rejoined and examined once claim 14, on which it depends, is allowed.

In the Office Action Summary, claims 49-51 are indicated to be rejected. However, these claims are not rejected in the Office Action. Thus, the Examiner is respectfully requested to clarify the status of these claims.

Replacement drawings were filed with the Amendment filed November 7, 2005. The Examiner is respectfully requested to indicate that these drawings have been accepted.

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Parkin in the July 20 personal interview. Applicants' separate record of the substance of the interview is set forth above regarding claim status and incorporated into the following remarks. It is Applicants' understanding that Examiner Parkin agreed with Applicants that SEQ ID NOS: 6, 9, and 12 are under examination.

Claims 1, 7-9, 14, 15, 28-30, 36-38, 40-42, 45-47, and 60-66 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Applicants respectfully traverse the rejection.

In rejecting the claims, the Examiner indicates that "the broadly recited claim language directed toward fragments, equivalents, and homologous sequences is unacceptable" (p. 5). However, claims 65 and 66 are not directed to such subject matter. Thus, the Examiner is respectfully requested to either allow or clarify the rejection of claims 65 and 66.

With regard to the other rejected claims, it is respectfully submitted that these claims are supported by the specification.

To provide written description for a claim, the specification as originally filed must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the

inventors were in possession of the invention as claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971). The Patent Office, therefore, must have a reasonable basis to challenge the adequacy of the written description. Specifically, the Patent Office has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the specification a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976).

As indicated in *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), an adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." In *Eli Lilly*, the Federal Circuit stated that a claim directed to human insulin cDNA was not adequately supported by the specification, which merely identified the cDNA by its principle biological activity, i.e., encoding human insulin, and a potential method for isolating it, without describing any structural features of the cDNA. *Id.* at 1567 In addition, the Federal Circuit stated that the description of rat insulin cDNA was insufficient to support claims that generically recite vertebrate or mammalian insulin cDNA. *Id.* at 1568. Thus, in *Eli Lilly*, the Federal Circuit held that providing no structural information about the claimed DNA was insufficient. However, the Federal Circuit did not hold, and has not held, that it is necessary to set forth an exact nucleotide sequence for any sequence within a claim, much less for more than one embodiment within a claim, in order to fulfill the written description requirement.

Instead, what is required for written description is a precise definition of the nucleic acid "sufficient to distinguish [the claimed material] from other materials." *Id.* at 1568. As

discussed below, the present specification provides a precise definition of the claimed nucleic acid in a manner that is sufficient to distinguish the claimed nucleic acids from other nucleic acids.

Unlike the situation in *Eli Lilly*, the present specification clearly provides more than a mere statement that the claimed nucleotide sequences are part of the invention and a reference to a potential method for isolating them. Instead, the specification clearly indicates that the inventors isolated and sequenced clones to obtain SEQ ID NOS: 6, 9, and 12. *See Examples 1-3 at paragraphs [0060] to [0088] of the substitute specification filed July 16, 2001.*

In addition to describing SEQ ID NOS: 6, 9, and 12, paragraph [0012] of the specification specifically describes nucleotide sequences having, for every series of 100 contiguous monomers, at least 70% identity with SEQ ID NO: 6, 9, or 12. This reference to nucleotide sequences having, for every series of 100 contiguous monomers, at least 70% identity with SEQ ID NO: 6, 9, or 12 provides substantial structural information about all the sequences encompassed in the present claims.

In particular, the specification provides sufficient structural information to distinguish the claimed nucleic acids from nucleic acids that are outside the scope of the claims, as was required by the Federal Circuit in *Eli Lilly*. That is, even though the specification does not set forth the nucleotide sequence of every nucleic acid within the claims, one of ordinary skill in the art could easily identify by its nucleotide sequence whether a particular nucleic acid has, for every series of 100 contiguous monomers, at least 70% identity with SEQ ID NO: 6, 9, or 12 and is thus within the scope of the present claims. As a result, the present situation can be clearly distinguished from the situation in *Eli Lilly* where a nucleic acid was identified merely by its principle biological activity. Instead, in the present case, the claimed nucleic acids are identified by distinguishing structural characteristics.

For at least these reasons, it is respectfully submitted that the specification clearly supports the claims of the present application. Therefore, the written description rejection should be reconsidered and withdrawn.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 7, 9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51, and 60-66 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



William P. Berridge
Registration No. 30,024

Kristin K. Vidovich
Registration No. 41,448

WPB:KKV/smo

Date: August 7, 2006

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461
--